March 9, 2018

CATS Tonometer, LLC
% Paul Kramsky
President, Rockin' Regulatory, Inc.
21831 Tumbleweed Circle
Lake Forest, CA 92630

Re: K173904
Trade/Device Name: CATS Tonometer Prism
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometer and Accessories
Regulatory Class: Class II
Product Code: HKY
Dated: December 22, 2017
Received: December 22, 2017

Dear Paul Kramsky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bradley S. Cunningham -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K173904

Device Name
CATS Tonometer™ Prism

Indications for Use *(Describe)*

The CATS Tonometer™ Prism is intended to be used with Goldmann type tonometers for the measurement of intraocular pressure.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary for the CATS Tonometer™ Prism

1. Submission Sponsor:

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2. Contact:

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Contact: Nannon Roosa, COO and CFO
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3. Date Prepared:

March 6, 2018

4. Device Name:

Trade/Proprietary Name:	CATS Tonometer™ Prism
Classification Name:	Tonometer and Accessories
Product Code:	HKY
Regulation Number:	21 CFR 886.1930

5. Predicate Devices:

The CATS Tonometer prism is substantially equivalent in terms of intended use and technological characteristics to the GOLDEN VISION (Goldmann) Manual Tonometer (K981432).

6. Device Description:

The CATS Tonometer™ Prism is used as an optical image prism for Goldmann applanation style tonometers. It is a modification of the standard Goldmann Applanation Tonometer (GAT) prism, with the only alteration being the modification of the flat surface in the GAT to a curved surface and a compensatory lengthening in the CATS prism. The CATS prism is made of PMMA, the corneal contact diameter is 7 mm and the total length of the prism is 30 mm.

7. Indications for Use:

The CATS Tonometer™ Prism is intended to be used with Goldmann type tonometers for the measurement of intraocular pressure.

8. Performance Data:

Non-Clinical Data

Design verification testing, , which consisted of optical and mechanical tests, demonstrated that the CATS Tonometer™ Prism met the design requirements articulated in ANSI Z80.10-2014. Bench testing was also performed in accordance with both ANSI Z80.10, Ophthalmic Instruments – Tonometers and FDA Guidance (March 27, 2006): Tonometers – Premarket Notification [510(k)] Submissions using human cadaver eyes. The primary purpose of this study was to statistically demonstrate that the null hypothesis is valid as far as the difference in IOP measurements between the CATS Tonometer™ Prism and the Goldmann (GAT) tonometer prism in accuracy and repeatability. The study indicated that the accuracy and both inter-operator as well as intra-operator repeatability met or exceeded the performance requirements of the reference GAT tonometer.

Clinical Data

The CATS Tonometer™ Prism was clinically evaluated in accordance with both ANSI Z80.10-2014, Ophthalmic Instruments – Tonometers and FDA Guidance (March 27, 2006): Tonometers – Premarket Notification 510(k) Submissions. The primary performance endpoint was accuracy of IOP measurement readings, as measured by applanation tonometry. The success criteria for the primary endpoint was that the CATS tonometer prism measurements to be within ± 5 mmHg of the GAT tonometer prism measurements. No more than 5% of the paired differences between the reference tonometer (CATS prism) and the test tonometer (GAT prism) readings for each pressure range, would be greater than the tolerance levels:

IOP range (mmHg)	**Tolerance of paired differences (mmHg)**
7 to 16	±5
>16 to < 23	±5
≥23	±5

The study population included adult population with a balanced distribution in sex and age. No statistically significant difference in IOP measurement was observed between the CATS tonometer prism and the reference GAT tonometer prism. No statistically significant difference in IOP measurement repeatability was observed between the CATS tonometer prism and the reference GAT tonometer prism with respect to inter-operator, intra-operator, as well as lot repeatability.

Conclusion

Based upon the non-clinical and clinical testing performed, the CATS Tonometer Prism is as safe, as effective, and performs as well as the predicate device. A comparison of the CATS Tonometer Prism and the predicate device is presented in Table 1.

9. Substantial Equivalence:

The claim of substantial equivalence to the previously cleared GOLDEN VISION (Goldmann) Manual Tonometer (K981432) is supported by the following comparison of characteristics in Table 1 and non-clinical and clinical performance data. Therefore, the CATS Tonometer Prism is substantially equivalent to the predicate device.

Table 1 - Comparison of CATS Tonometer™ and GAT Prisms

Characteristic	CATS Tonometer™	Goldmann Tonometer (GAT)
Indications for use	To be used with Goldmann type tonometers for the measurement of intraocular pressure of the human eye.	To be used for the measurement of intraocular pressure of the human eye.
Overall prism length	30.0 mm	Same
Base diameter	10.96 mm	Same
Contact surface diameter	7.0 mm	Same
Bi-prism diameter	6.0 mm	Same
Bi-prism length to corneal contact at full applanation diameter	10.67 mm @ 3.29 mm	10.0 mm @ 3.06 mm
Bi-prism angle	30°	Same
Index of refraction	1.4906	Same
Prism construction material	PMMA	Same
Prism component adhesive	USP Class VI	Same
Prism contact surface	Concave-convex contoured	Flat
Prism surface finish	Optical polish	Same
Applanating area – diameter	3.29 mm	3.06 mm
Force to IOP conversion	1.0 g = 10 mmHg	Same